NOTIFICATIONS – HSE RGMS Framework

1.

From: Beaumont Ethics <beaumontethics@rcsi.ie>
Sent: Friday, September 24, 2021 4:41 PM
Subject:

Research Governance - HSE and HSE funded organisations - Insurance / Indemnity Update -

Dear Colleague

1. Please be aware that the HSE Framework for the Governance, Management and Support of Health Research was launched on the 9th September 2021 – this document is of assistance in identifying the role of each of the organisations involved in an individual research study - https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf

The following excerpt from the framework is relevant in respect of indemnity and insurance for research studies taking place in Beaumont Hospital {Beaumont Hospital is a Delegated State Authority (DSA)}: -

Indemnity and Insurance:

"Clinical Indemnity Scheme (CIS):
• CIS cover automatically applies to DSA-approved non-interventional health research that is conducted by DSA staff in a DSA premises where the trial/ research subjects are HSE patients.

• Health research undertaken as part of third-level institution research studies, i.e. PhD/MSc studies, is subject to the requirements of the HSE Framework for the Governance, Management and Support of Research. Patient interventions must be supervised by a DSA clinician in order for the CIS to apply. Other appropriate insurance may be required and must be provided by the third-level institution.

• A number of conditions must be met in order for the CIS to apply to clinical trials, interventional trials, or studies and regulated research where there is a third party sponsor, e.g. a third-level institution, pharmaceutical company or other commercial company. This includes research ethics approval, a DSA clinician acting as the PI, a signed clinical trial indemnity form, and clinical trial insurance and product liability cover with adequate limits of indemnity. These conditions must be verified by the SCA or a designated representative of the SCA.

• In situations where a DSA acts as the sponsor of clinical trials, interventional trials or studies, or regulated research, there may be added insurance requirements independent of the General Indemnity Scheme/CIS cover, e.g. product liability insurance, or no fault compensation.

Please contact the SCA for further guidance.

General Indemnity Scheme (GIS):
• GIS cover applies to the health research activities of a DSA and its staff. External parties must have their own insurance in place to cover the activities of their organisation/staff, i.e. employers' insurance and public liability insurance policies with adequate limits of indemnity.

Further details and guidance can be found at www.stateclaims.ie, or by emailing the SCA: stateclaims@ntma.ie"

2. Separately, please be advised that the State Claims Agency released an updated Clinical Trial Indemnity Form on the 18th August 2021**: https://www.beaumontethics.ie/application/indemnity.htm**

2.

From: Beaumont Ethics <beaumontethics@rcsi.ie>
Sent: Tuesday, September 28, 2021 11:19 AM
Subject:

HSE Framework - Naming Organisations as opposed to individuals....

Dear All

Please note that the HSE launched a new framework for the Governance, Management and Support of Research on the 9th September 2021 https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf - as such there has been a shift towards naming organisations as data controllers and processors (as opposed to employees or principal investigators) and also, in terms of clinical trials only, ensuring that an organisation is sponsoring the clinical trial.

Please note that this is the first time that there has been a formal published position from the HSE in this area.

Researchers seeking to conduct research in the HSE or a HSE funded organization will increasingly be required to focus on identifying the organisations involved and their role in respect of an individual research study

Data Protection Officers in various HSE or HSE funded organisations will release updated documentation in due course.

3.

From: Beaumont Ethics <beaumontethics@rcsi.ie>
Sent: Tuesday, October 5, 2021 12:14 PM
Subject:

HSE RGMS Framework / Investigators with Dual Appointments / Dual Affiliations

Dear All

Further to launch of a new framework for the Governance, Management and Support of Research on the 9th September 2021 https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf - please be aware that as part of the increasing emphasis on **organisations** being named as data controllers and data processors – as opposed to individuals, employees, or investigators,
that where an investigator seeking to conduct research in the HSE or a HSE funded organisation holds a **dual appointment/dual affiliation**, that the following quote from the Framework will apply:

*'Where HSE staff hold a dual affiliation, they must decide **which organisation** (i.e. the HSE, or the academic/other organisation) they will represent for the whole duration of the research study…… This is a vital requirement for the correct determination of controllership between the collaborative organisations.'* - Page 26

Data Protection Officers in various HSE or HSE funded organisations will release updated documentation in due course.